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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier A. Corbin

Food and Drug Administration

[Docket No. 02N–0077]

Agency Emergency Processing Under OMB Review; Emergency Medical Device Shortage Program Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns a telephone survey used to assist FDA in implementing an emergency medical device shortage program so that the agency can respond quickly to medical device shortages that might arise in the aftermath of a bioterrorist attack.

DATES: Submit written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 10503, Attn: Stuart Shapiro, Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13).

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This information is needed immediately so that the agency can respond quickly to medical device shortages that might arise in the aftermath of a terrorist attack.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Emergency Medical Device Shortage Program Survey

Under section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(d)(2)), the Commissioner of FDA is authorized to implement general powers (including conducting research) to carry out effectively the mission of FDA. Section 510 of the act (21 U.S.C. 360) requires that domestic establishments engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution register their establishments and list the devices they manufacture with FDA. Section 522 of the act (21 U.S.C. 360(l)) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health, or gross deception of the consumer. These sections of the act enable FDA to enhance consumer protection from risks associated with medical devices usage that are not foreseen or apparent during the premarket notification and review process.

FDA is compiling a list of medical devices that would be needed to treat patients in the event of a biological or chemical weapon attack. FDA plans to collect manufacturing and inventory information concerning the devices on this list, starting with those devices that are considered critical to patient care. This information will allow FDA to identify quickly sources and locations

of medical devices in the event that they are needed in an emergency. It will also help to identify logistical problems in the event that borders are closed or transportation has been disrupted. In addition, FDA plans to maintain a list of telephone contacts for the manufacturers so that communication channels with manufacturers will be in place in the event that they are needed.

This telephone survey's primary respondents will be medical device manufacturers and wholesalers.

FDA estimates the burden of this collection of information as follows:

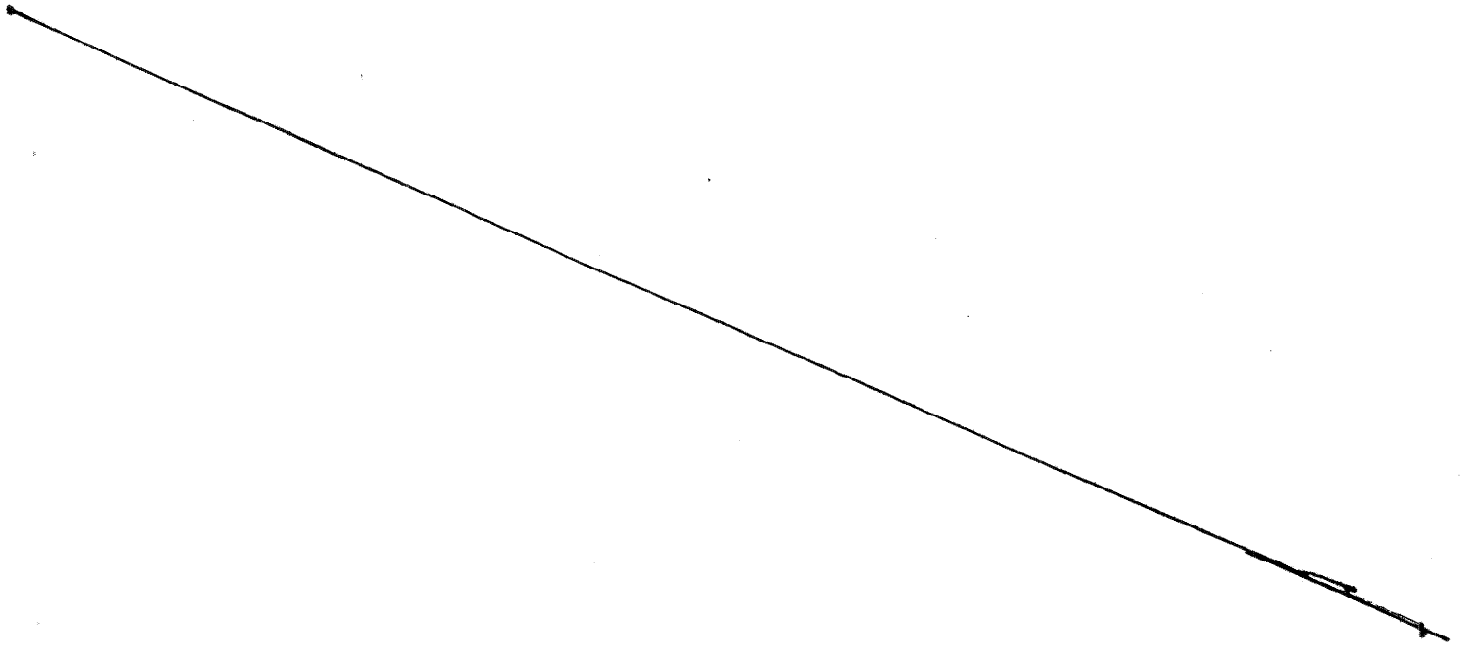
TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	No. of Respondents	Annual Frequency per-Response	Total Annual Responses	Hours per Response	Total Hours
Telephone Survey	7,000	1	7,000	.1	700

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA has based these estimates on conversations with industry and trade association representatives, and from internal FDA estimates.

The total number of manufacturers is estimated to be 70,000. FDA estimates that approximately 10 percent of these manufacturers would be contacted in a 1-year period, due to limitations on FDA staff. It is estimated also that the survey will take approximately 6 minutes to complete over the telephone. Therefore, 7,000 respondents (10 percent of the FDA manufacturer base) times 1/10 of an hour (i.e., 6 minutes) would equal a total of 700 hours.



Dated: 3-19-02

March 19, 2002.

Margaret M. Dotzel

Margaret M. Dotzel,
Associate Commissioner for Policy.

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